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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,105	06/20/2003	J. Fernando Bazan	DX0903K1B	7017

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EXAMINER	
JALLA, SANJOO	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,105	BAZAN ET AL.	
	Examiner	Art Unit	
	Sanjoo Shree Jalla	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

1. The examiner of this application in the PTO has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Sanjoo Jalla, Group Art Unit 1644, Technology Center 1600.

2. Claims 1-20 have been cancelled and claims 21-40 are under consideration in the instant application.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

4. The abstract of the disclosure is objected to as not accurately describing the claimed invention. Correction is required. See MPEP § 608.01(b).

5. Applicant's information disclosure, filed 7/21/03 and 8/24/05 is acknowledged. References AE and AH were not found and have been lined through and have not been considered.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. The instant application claims the benefit of priority to the provisional application Serial No. 60/101,318, filed 09/21/1998. Applicant is advised that because the specific, substantial and credible utility of the instant polypeptide consisting SEQ ID NO: 2 is only disclosed in the specification of continuation application 09/963,347 filed on 09/25/2001, the effective filing date for the instant invention is determined as the filing date of continuation application 09/963,347 i.e. 09/25/2001.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The word "means" is preceded by the word(s) "comprising a" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

It is necessary for the words that precede "means" to convey a function to be performed. The phrase "comprising a means" does not convey any function to be performed. Even if "comprising a means" is restated as "means for comprising a", the phrase makes no sense because the word "comprising a" has no functional connotation, and the phrase is indefinite.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-40 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) An isolated binding compound that specifically binds a polypeptide consisting of SEQ ID NO: 2 (claim 21).

B) The binding compound that is a neutralizing antibody (Claim 27).

C) The binding compound is raised against a purified or recombinantly produced polypeptide comprising SEQ ID NO: 2 (claim 31) and raised against an antigen comprising at least 8 contiguous amino acids (claim 32) and raised against an antigen comprising at

least 12 contiguous amino acids (claim 33) from SEQ ID NO: 2.

D) The antigen comprises the at least 8 contiguous amino acids from SEQ ID NO: 2 conjugated to an immunogenic protein (claim 35).

E) The detection kit, wherein the detection is performed using enzyme-linked immunosorbent assay (ELISA) (claim 39).

In the Preliminary Amendment, filed 3/15/02, Applicant indicates that support for the new limitations of Claims 37, 38, and 40 can be found at pages 30-32 of the specification and that support for the new limitations of Claims 43, 44, and 46 can be found at page 11.

A review of the specification fails to reveal support for the new limitations.

Regarding A), note that the invention claimed is much broader than the original claim which is limited to a binding site of an antibody and not the entire binding compound, and further which specifically binds to at least 17 contiguous amino acids from SEQ ID NO: 2 or 4 and not as claimed in new claim 21 where it specifically binds to SEQ ID NO: 2 and not a portion of it.

As claims 22-40 are dependent on claim 21 and read on limitation of claim 21 so they are also rejected under new matter where the binding compound is not limited to a binding site of an antibody and which specifically does not bind to at least 17 contiguous amino acids from SEQ ID NO: 2 of original claim.

Regarding B), the Preliminary Amendment, filed 8/18/04, Applicant indicates that support for the new limitations of Claim 27 can be found at page 24, lines 20-21.

A review of the specification fails to reveal support for the new limitations.

Page 24, lines 20-21 of specification mentions usefulness of neutralizing antibodies but does not mention the binding compound to be a neutralizing compound.

Regarding C), the Preliminary Amendment, filed 8/18/04, Applicant indicates that support for the new limitations of Claims 31-34 can be found at page 20, lines 23-26, page 13, lines 10-19 and page 29, lines 19-25.

A review of the specification fails to reveal support for the

new limitations.

Page 20, lines 23-26 of specification mentions antibodies raised against amino acid sequences encoded by nucleotide sequence shown in SEQ ID NO: 1 or 3, or fragment of proteins containing it but it does not mention the binding compound raised against a purified or recombinantly produced polypeptide hence does not support claim sufficiently.
Further, page 13, lines 10-19 of specification mentions amino acid residues of a polypeptide to be " at least about 8 amino acids, generally at least 12 amino acids" whereas claims 32 and 33 recite "at least 8 contiguous amino acids" (claim 32) and "at least 12 contiguous amino acids" (claim 33). This generic disclosure is insufficient support for claims reciting number of amino acids of an antigen. e.g., at least as claimed means any number of amino acids greater than 8 but at least about 8 amino acid could mean any number of amino acids.

Regarding D), in the Preliminary Amendment, filed on 8/18/04, Applicant indicates that support for the new limitations of Claim 35 can be found at page 22, lines 18-21.

A review of the specification fails to reveal support for the new limitations.

Page 22, lines 18-21 of specification mentions that antibodies can be raised by immunization of animals with conjugates of the fragments with immunogenic proteins but it does not mention that the antigen comprises the at least 8 contiguous amino acids from SEQ ID NO: 2 conjugated to an immunogenic protein. Disclosure has insufficient support for claim 35.

Regarding E), in the Preliminary Amendment, filed on 8/18/04, Applicant indicates that support for the new limitations of Claim 39 can be found at pages 42, line 42 to page 43, line 12).

A review of the specification fails to reveal support for the new limitations.

Specification (pages 42-43, line 12) mentions usefulness of antibodies but does not mention a detection kit wherein the detection is performed by using ELISA. This generic disclosure is insufficient support for claims reciting specific detection assay, e.g., ELISA. The specification directs to a reference " Current Protocols in Immunology" but does not mention anything about the detection kit; hence disclosure has insufficient support for claim 39.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that forms the basis for the rejection under this section made in this office action:

A person shall be entitled to a patent unless-

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-23, 26-28 and 31-35 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,555,520.

The '520 Patent teaches a protein called thymic stromal lymphopoietin (TSLP) that has 91.9% identity with amino acid sequence of SEQ ID NO: 2 of instant application (see a copy of printout of the sequence alignment attached to the office action). Further, '520 Patent teaches monoclonal antibodies that bind TSLP (see page 51, Example 5, Left column).

Further, antibody of '520 Patent that binds TSLP protein will bind polypeptide consisting of SEQ ID NO: 2, as it is an inherent property of an antibody to bind to a protein that has 91.9% homology to the protein it binds to. Further, resulting antibody would be expected to bind the polypeptide with a K_D of 10μM or less.

The reference clearly anticipates the invention.

11. Claims 24, 25, 29 and 30, are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,555,520 as applied to claims 21-23, 26-28 and 31-35 above, and in further view of Gavilondo et. al. (BioTechniques, 2000; 29: 128-145).

U.S. Patent No. 6,555,520 has been discussed previously.

U.S. Patent No. 6,555,520 does not teach the antibody to be either chimeric or humanized or single chain Fv or a Fab fragment.

Gavilondo et. al. teaches that it was well known in the art at the time the invention was made to prepare antibody fragments (Fv, Fab

or $F(ab)_2$) (see page 133, left hand column, second paragraph), chimeric antibodies, humanized antibodies or single chain antibodies as these are useful for a number of procedures including purification (e.g. affinity chromatography). Further, Gavilondo et. al. teaches the usefulness of monoclonal antibodies and the antibody fragments for therapeutic purposes. In addition, Gavilondo et.al. teaches that antibodies can be produced as genetic fusion proteins with enzymes and other functional groups (i.e. detectable labels) (see page 132, right hand column, 3rd paragraph).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to apply the teachings of Gavilondo et. al. to make a chimeric or humanized or single chain Fv or a Fab fragment antibody that would bind the TSLP protein of the '520 Patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to make antibodies (chimeric or humanized or single chain or a Fab fragment antibody) to TSLP protein that would bind SEQ ID NO: 2 because as taught by Gavilaondo et. al., chimeric, humanized and antibody fragments are useful for a number of procedures including purification (e.g. affinity chromatography) and detection assays as well as diagnostic and therapeutic regimens because of their smaller size and potentially better tissue penetration and clearance (see page 132, left column-second paragraph, lines 7-12).

From combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

12. Claims 36-38, are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,555,520 as applied to claims 21-23, 26-28 and 31-35 above, and in further view of U.S. Patent No: 4,281,061.

U.S. Patent No. 6,555,520 has been discussed previously.

U.S. Patent No. 6,555,520 does not teach a detection kit comprising the binding compound and instruction material and a compartment for storage of the binding compound.

The '061 Patent teaches that reagents for an immunoassay can be provided as kits as a matter of convenience and to optimize the sensitivity of the assay in the range of interest (column 22, line 62 to column 23, line 4).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include an antibody that binds TSLP protein (and, therefore binds protein of SEQ ID NO: 2) as taught by the '520 Patent, in a kit format for the convenience and economy of the user as taught by the '061 Patent. One would have been motivated to assemble the reagents in a kit format to standardize the reagents for optimization convenience.

From combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

13. Claims 39-40, are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,555,520 and U.S. Patent No: 4,281,061 as applied to claims 21-23, 26-28 and 31-38 above, and in further view of U.S. Patent No: 5,627,043 issued May 6, 1997.

U.S. Patent No. 6,555,520, and U.S. Patent No: 4,281,061 have been discussed previously.

U.S. Patent No. 6,555,520, and U.S. Patent No: 4,281,061 do not teach a detection kit wherein the detection is performed by using ELISA and for separating bound binding compounds from free binding compounds.

The '043 Patent teaches that the kit can contain a primary antibody that selectively binds to cleaved product, which can be used in, for example, an enzyme immunoassay or immunoprecipitation assay. (see Detailed Description Text (51)).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include necessary reagents to perform an enzyme immunoassay or immunoprecipitation assay as taught by the '043 Patent, for the detection of TSLP protein (and, therefore protein of SEQ ID NO: 2) as taught by the '520 Patent, in a kit format for the convenience and economy of the user as taught by the '061 Patent. One would have been motivated to assemble the reagents in a kit format to standardize the reagents for optimization and convenience.

From combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sanjoo Jalla whose telephone number is (571) 272-4453. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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10/24/08
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